

### **REMARKS**

Claims 2, 3, 5-10, 24, 36-42 and 68-72 were pending at the time of the Office Action, with claims 24, 36-42, 68, 69 and 71-72 in active prosecution.

Although claim 68 is amended above, this amendment is primarily to combine the limitations of claim 69 into claim 68, as well as to add a limitation to the seat ring. As such, no further searching should be required, so entry of the Response and allowance of the case is earnestly requested.

#### **Restriction/election**

The Examiner's withdrawal of claim 70 is mooted by the cancellation of the claim.

#### **Specification**

The Examiner's statements about Figs 12A and 12B indicate a possible misunderstanding of the applicant's statement made by the undersigned attorney in the document filed by the applicant on 3 April 2008. To quote the statement made on behalf of applicant: "In Figs 12A, 12B, the fastener head 404 has the required larger diameter, without the seat ring." This is not to say that Figs 12A and/or 12B do not show the seat ring – it says merely that the head size renders the seat ring superfluous, although it is clearly shown (although not numbered).

#### **Claim amendments**

First, please note that all "withdrawn" claims (2, 3, 5-10 and 70) have been cancelled to put the case in condition for allowance if the amendment to claim 68 renders the case allowable.

In response to the Examiner's rejection under §112, second paragraph, regarding the term "seat sleeve" in claim 69, the applicant respectfully notes that this issue is technically mooted by the cancellation of claim 69, but that the Examiner's point is well-taken and has been accounted for in the amendments to claim 68. The same applied to the Examiner's rejection under §112, second paragraph, regarding the term "enlarged head" in claim 69.

Further, the applicant has introduced the adjective "non-resilient" to modify the term "seat ring" to distinguish the newly-cited reference US Pat 6,063,090 to Schlapfer ("Schlapfer '090"). While the term "non-resilient" is not found in the specification as filed (the reference to the seat ring 426 is found at page 6, second full paragraph of the

specification), it is clear from the description (including the use of the term “ring”) and the drawings that the non-resilient property would have been understood by one of skill in this art at the time of the invention. In contrast, Schlapfer ‘090 refers to the corresponding structure 7 as a “spring chuck” that allows the head of a pedicle screw to be snapped into it.

Rejections under 35 USC 103(a)

Claims 68, 71 and 36 are rejected as obvious over a combination of Sherman ‘350 with Bono ‘829, a rejection previously made against claims 30-34 and 37-42. Applicant respectfully traverses. As with the Schlapfer ‘090 spring chuck 7, Sherman ‘350 teaches a resilient collet 13, either of which are expandable to allow a pedicle screw head to be snapped into place. The non-resilient screw ring 426, as now claimed, requires that the intermediate length of the pedicle screw be passed through the open bottom end of the rod retention assembly before the pedicle screw is driven into bone, as it cannot be expanded in the manner of the cited references.

The Examiner has also rejected claims 36-42, 68, 69, 71 and 72 as obvious over the combination of US Pat 6,063,090 to Schlapfer (“Schlapfer ‘090”) with Bono ‘829. Applicant respectfully traverses, for the reasons cited about the resiliency that is inherent in the spring chuck 7 of Schlapfer ‘090.

The solid or non-resilient nature of the seat ring in the present application is an important feature that distinguishes the prior art cited. The specification, in fact, states that this is a “significant improvement over known designs.” Page 6, second full paragraph.

In providing the “advantage” of being able to pop a pedicle screw that has already been driven into the bottom of a tulip or cup rod holder, both Sherman ‘350 and Schlapfer ‘090 sacrifice strength of holding the screw head in place. Sherman ‘350 uses a collet that resiliently grabs the top of the screw head and Schlapfer ‘090 uses the spring chuck to resiliently grab the bottom of the screw head. If either of these approaches were sufficiently reliable, one would expect that a resilient shape would be provided to the bottom of the cup itself.

The non-resilient seat ring, as an intermediate element between the screw head and the cup, can provide an interference fit that allows a locking force to be applied at a

lower level of axial force than in other designs. The significant improvement is over both the slotted designs of Sherman '350 or Schlapfer '090 and the absence of an intermediate structure between the screw head and the cup.

The gravity of the screw head dislocating from the cup simply cannot be understated. This device is surgically placed in the spine of a human, so it is not amenable to periodic tightening. It is proximate to the aorta, which, if nicked, could result in death. The bone structures retained in place by the rod system are proximate to the spinal column, where important nerves (or the spinal column itself) could be damaged if the rod system fails.

In terms of the obviousness rejection rationales approvingly cited by the Supreme Court holding in *KSR v Teleflex*, the rejections made by the Examiner appear to be of the "combining prior art elements according to known methods to yield predictable results" type. To the extent that the cap of Bono '829 can be predictably combined with the overall rod retainer body of either Sherman '350 or Schlapfer '090, applicant acknowledges the propriety of that combination.

However, neither Sherman '350 nor Schlapfer '090 teach the use of "a bone screw and a non-resilient seat ring" as now claimed in claim 68, and the use of that particular combination allows the unexpected results of a smaller profiled head and screw thickness relative to the tulip opening, as taught in the specification at page 6, second full paragraph.

Accordingly, the Examiner has not made a prima facie case of obviousness against claim 68 as amended, and allowance is requested.

Respectfully submitted,

Dated: 9 September 2008

By: /Stephen L Grant, Reg No 33390/

Stephen L. Grant  
Reg No 33,390  
Standley Law Group LLP  
495 Metro Place South, Suite 210  
Dublin, Ohio 43017-5315  
Telephone: (614) 792-5555